



Billing Code 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2018-0048]

Updated Labeling Guideline on Statements That Bioengineered or Genetically Modified Ingredients or Animal Feed Were Not Used in the Production of Meat, Poultry, or Egg Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of availability and response to comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the availability of an updated version of its guideline on how establishments can make label claims concerning the fact that bioengineered or genetically-modified (GM) ingredients or animal feed were not used in the production of meat, poultry, or egg products. For purposes of this guidance document, these claims are referred to as "negative claims." The updated document reflects changes made in response to comments received after announcement of the guideline in an August 2016 **Federal Register** notice.

ADDRESSES: A downloadable version of the compliance guideline is available to view and print at http://www.fsis.usda.gov/Regulations_&_Policies/Compliance_Guide

s_Index/index.asp. No hard copies of the compliance guideline have been published.

FOR FURTHER INFORMATION CONTACT: Terri Nintemann, Assistant Administrator, Office of Policy and Program Development by telephone at (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

Under the Federal Meat Inspection Act, Poultry Products Inspection Act, and Egg Products Inspection Act (21 U.S.C. § 601 *et seq.*; 21 U.S.C. § 451 *et seq.*; 21 U.S.C. § 1031 *et seq.*) (the Acts), FSIS develops and implements regulations and policies to ensure that the labels of meat, poultry, and egg products are truthful and not misleading. Under the Acts, the Secretary of Agriculture, who has delegated this authority to FSIS, must approve the labels of meat, poultry, and egg products before the products can enter commerce (21 U.S.C. 601(d); 21 U.S.C. 457(c); 21 U.S.C. 1036(b)).

FSIS has a prior-approval program for labeling.¹ FSIS allows certain labels that bear only mandatory labeling features and that comply with the Agency's labeling regulations to be

¹ See FSIS Directive 7221.1 at <https://www.fsis.usda.gov/wps/wcm/connect/9a2ebc76-2d43-4658-841a-f810b1f65f04/7221.1.pdf?MOD=AJPERES>.

generically approved (9 CFR 412.2(a)(1)). However, a label with a special statement or claim,² including a negative claim, must be submitted to FSIS for approval before it may be used on a product distributed in commerce (9 CFR 412.1(c)(3) and 412.1(e)). A label bearing a negative claim must be submitted to the Office of Policy and Program Development, Labeling and Program Delivery Staff, in FSIS, with necessary documentation to support the special statement or claim. Examples of negative claims include but are not limited to: "Product contains no genetically-modified ingredients," and "Product made from poultry that were not fed genetically-engineered feed."

On August 24, 2016, FSIS announced the availability of and requested comments on its *Labeling Guideline on Statements That Bioengineered or Genetically-Modified Ingredients or Animal Feed Were Not Used in Meat, Poultry, or Egg Products* (81 FR 57879). FSIS developed the guideline for establishments that want to make label claims concerning the fact that bioengineered or GM ingredients were not used in a meat, poultry, or egg product. The guideline also provides information on how establishments

² Special statements and claims are claims, logos, trademarks, and other symbols on labels that are generally not defined in FSIS regulations or the *Food Standards and Labeling Policy Book*. For specific examples, see Appendix 1 at <https://www.fsis.usda.gov/wps/wcm/connect/bf170761-33e3-4a2d-8f86-940c2698e2c5/Label-Approval-Guide.pdf?MOD=AJPERES>.

can make label claims that a product was produced from livestock or poultry that were not fed bioengineered or GM feed. As stated in the summary, for purposes of this guidance document and hereinafter, these claims are referred to as "negative claims."

After reviewing the comments received, the Agency has revised the guideline to clarify that FSIS approves negative claims verified under a third-party certifying organization the same way it approves other special statements or claims and will not limit claims to those consistent with AMS's definition of bioengineering, in Pub. L. 114-216. FSIS also added information about the certification and labeling for certified organic products. Specifically, certified organic products may be labeled with negative claims without additional third-party certification or documentation when the negative claim is connected with an asterisk or other symbol to the explanatory statement "Produced in compliance with the USDA Organic Regulations" and that the website of the certifying entity does not always need to appear on the label. The revised guideline is posted at: <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index>. Although comments will no longer be accepted through www.regulations.gov on this

guideline, FSIS will update this document as necessary if new information becomes available.

Comments and FSIS Responses

FSIS received 201 comments on the *Labeling Guideline on Statements That Bioengineered or Genetically-Modified Ingredients or Animal Feed Were Not Used in Meat, Poultry, or Egg Products*. Most comments were submitted by individuals who strongly supported food labeling for genetically engineered foods. In addition, FSIS received 12 comments from consumer-advocacy organizations, agriculture-specific trade coalitions/associations, organic farmers, and a trade association representing the poultry industry.

Many of the issues raised in the more detailed comments concerned how the statutory definition of “bioengineering” in Pub. L. 114-216³ should be interpreted and applied by USDA’s Agricultural Marketing Service (AMS). FSIS believes these comments are beyond the scope of the guideline. However, the same issues were raised in responses to questions posted in 2017 by AMS as part of the development of the proposed National Bioengineered Food Disclosure Standard (NBFDS). On December 21, 2018, AMS addressed these and other issues in the NBFDS final

³ Available at <https://www.congress.gov/bill/114th-congress/senate-bill/764>.

rule (83 FR 19860).⁴

Following is a summary of the relevant issues raised in the comments and FSIS's responses.

Applicability

Comment: Comments from consumer-advocacy organizations and agriculture-specific trade coalitions/associations strongly opposed the statement in the 2016 guidance document - "FSIS will utilize the definition of "bioengineering" in Pub. L. 114-216 when evaluating negative claims" (AMS's definition). The comments said FSIS should not use AMS's definition because it directly conflicts with Section 294(c) of Pub. L. 114-216, creates consumer confusion, and may complicate international trade. According to the comments, FSIS should instead use the Food and Drug Administration's (FDA's) definition of "modern biotechnology." They said the FDA definition is widely accepted and matches the definition recognized by key trade partners.

Response: It was never FSIS's intention to limit negative claims to those consistent with the definition of "bioengineering" in Pub. L. 114-216. FSIS has been and will continue to approve negative claims verified by a third-party

⁴ Available at <https://www.govinfo.gov/content/pkg/FR-2018-12-21/pdf/2018-27283.pdf>.

certifying organization with standards based on FDA's definition of "modern biotechnology" or with standards based on AMS's definition of "bioengineering." However, in response to these comments, FSIS has updated the guideline by removing the statement in question and to clarify that we approve negative claims consistent with our longstanding practice for other special statements and claims verified by a third-party certifying organization. If the negative claim is truthful and the producing establishment submits documentation demonstrating that the third-party certifying organization's program for the claim is being followed, FSIS will approve the negative claim.

Comment: Several comments contained details about how AMS's definition of "bioengineering" differs from FDA's definition of "modern biotechnology." The comments said that because of the differences, the same negative claim may reflect different standards depending on which definition the third-party certifier's program is based. They argued this results in negative claims that are inconsistent and potentially misleading to consumers.

Response: FSIS recognizes that negative claims may reflect different standards depending on the certifying entity's standards for the claim. However, FSIS disagrees that these

differences result in claims that are misleading or confusing to consumers.

As noted above, the labeling requirements for meat, poultry, and egg products in the Acts and implementing regulations are aimed at preventing product misbranding. To prevent labeling claims that are false and misleading, any label with a special statement or claim, including a negative claim, must be submitted to FSIS for prior-approval (9 CFR 412.1(c)(3) and 412.1(e)). FSIS comprehensively evaluates label approval applications on a case-by-case basis. Further, FSIS often consults with its Federal partners, e.g., the AMS and FDA, to decide whether the documentation submitted in support of a claim provides the level of detail needed to ensure that the claim is truthful and not misleading.

For FSIS to approve a label with a negative claim related to bioengineering, the producing establishment must submit documentation that supports it is complying with standards established by a third-party certifying organization, the third-party certifier's standards must be publicly available on a website, and the label must disclose a website address where consumers can obtain additional information regarding the claim

and the third-party's certification process.⁵

FSIS considers its current procedure of comprehensively evaluating approval requests for labels bearing negative claims on a case-by-case basis as sufficient to provide assurance that these labels are truthful and not misleading. Moreover, under the conditions described in the guideline, the labeling includes the information that consumers need to determine whether the negative claim meets their expectations for the claim.

We note establishments do not have to use any of the negative claims listed in the guideline, and that an establishment's decision to use a particular third-party certifier is a voluntary business decision.

Comment: Comments from consumer-advocacy organizations and agriculture-specific trade coalitions/associations argued FSIS should only allow negative claims on products that do not contain bioengineered ingredients *and* that are derived from livestock or poultry that were not fed bioengineered or GM feed because it reflects consumer expectations for these claims.

Response: FSIS disagrees. The guideline explains that, for FSIS to approve a negative claim on product labeling, the label

⁵ Products certified as "organic" would not need to disclose a website address on the label, except when the address is required under 7 CFR part 205.

must also bear a website address where consumers can obtain additional information regarding the claim and the third-party organization's certification process. With this approach, the labeling includes the information consumers need if unaware of the specific standards on which the negative claim is based. Thus, FSIS will continue allowing negative claims on products that do not contain bioengineered ingredients and/or that are derived from livestock or poultry that did not consume bioengineered feed when the producing establishment provides evidence that substantiates the claim. Likewise, FSIS will continue to allow the use of synonymous terms such as "genetically engineered" or "GE."

Comment: Comments from a trade association representing the poultry industry and consumers urged FSIS to clarify in the guideline that an animal is not considered genetically engineered merely because it consumed genetically engineered feed.

Response: Pub. L. 114-216 prohibits a food derived from an animal "to be considered a bioengineered food solely because the animal consumed feed produced from, containing, or consisting of a bioengineered substance" (7 U.S.C. 1639b(b) (2) (A)). FSIS agrees this means that the animal from which the meat or poultry

component was derived would not be considered bioengineered solely on the basis of the animal's feed. However, FSIS believes this information is outside the scope of the guideline, as the guideline provides only for negative claims that pertain to the non-animal ingredients, e.g., "no GMO ingredients" or "made without GE ingredients."

Minimum Standards

Comment: Comments from consumer-advocacy organizations, agriculture-specific trade coalitions/associations, and individuals said FSIS should set minimum standards in the guideline for negative claims and not allow negative claims on products that do not meet these standards.

Response: FSIS does not regulate biotechnologies and, thus, does not have the expertise to determine whether a particular third-party certifying organization's standards should represent a particular negative claim. To ensure negative claims continue to accurately reflect the standards on which they are based, FSIS will continue to evaluate labels bearing these claims on a case-by-case basis and, when needed, consult with Federal agencies with expertise in the matter. FSIS will approve a negative claim if it is truthful and adequately substantiated by the producing establishment.

Organic Certification

Comment: Comments from organic farmers and agriculture-specific trade associations urged FSIS to update the guideline to clarify that the *Organic Certificate* is sufficient support for negative claims, such as "non-GMO" and "not bioengineered." The comments also said a website is unnecessary on certified-organic product labels.

Response: FSIS agrees. For food certified under the USDA organic regulations, Pub. L. 114-216 states, "the certification shall be considered sufficient to make a claim regarding the absence of bioengineering in the food, such as "not bioengineered", "non-GMO", or another similar claim." Furthermore, certified-organic products would not need to disclose a website address on the label, except when the address is required under 7 CFR Part 205. FSIS has updated the guideline by adding this information.

Congressional Review Act

Pursuant to the Congressional Review Act at 5 U.S.C. 801 et seq., the Office of Information and Regulatory Affairs has determined that this notice is not a "major rule," as defined by 5 U.S.C. 804(2).

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication online through the FSIS Web page located at: http://www.fsis.usda.gov/federal-register_. FSIS also will make copies of this publication available through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

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Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250-9410.

Fax: (202) 690-7442.

Email: program.intake@usda.gov.

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Done in Washington, DC:

Carmen M. Rottenberg,
Administrator.

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